

WHAT IS CLAIMED IS:

1 1. A medical article sterilization device comprising:
2 a pretreatment area for medical articles, the pretreatment area having a heat
3 source to heat the medical articles;
4 a device to form a housing in a first web;
5 an article loading station where a medical article heated in the pretreatment area
6 is loaded into the housing in the first web;
7 an alignment device to align a second web with the first web; and
8 a sterilization-sealing station where the first web and the second web, with the
9 medical article loaded into the housing are sterilized and then the first and second webs are
10 sealed together.

1 2. A medical article sterilization device according to claim 1, wherein the
2 sterilization-sealing station further comprises gas injection pins to inject gas into the housing,
3 between the first and second webs.

1 3. A medical article sterilization device according to claim 2, wherein the
2 sterilization-sealing station further comprises a steam source to inject steam into the housing,
3 between the first and second webs.

1 4. A medical article sterilization device according to claim 1, wherein the
2 sterilization-sealing
3 station further comprises a steam source to supply steam to the housing.

1 5. A medical article sterilization device according to claim 1, wherein:
2 substantially no moisture is supplied to the medical articles at the sterilization-
3 sealing station, and
4 the pretreatment area has a steam source to supply moisture to the medical
5 articles.

1 6. A medical article sterilization device according to claim 5, wherein:
2 the sterilization-sealing station comprises a vacuum source and a controller,
3 the vacuum source evacuates the housing,
4 evacuating the housing removes moisture from the medical articles, and
5 the controller maintains the pressure in the housing so as to allow some moisture
6 to remain with the medical articles.

1 7. A medical article sterilization device according to claim 6, wherein the
2 controller maintains the pressure in the housing so as to allow the relative humidity in the
3 housing to be at least 40 % during sterilization gas exposure.

1 8. A medical article sterilization device comprising:

2 a device to form a housing in a first web;
3 an article loading station where a medical article is loaded into the housing in
4 the first web;
5 an alignment device to align a second web with the first web; and
6 a sterilization-sealing station where the first web and the second web, with the
7 medical article loaded into the housing are sterilized and then, the first and second webs are
8 sealed together, the sterilization-sealing station comprising gas injection pins to inject gas into
9 the housing, between the first and second webs.

10 9. A medical article sterilization device according to claim 8, wherein the
11 sterilization-sealing station further comprises a steam source to inject steam into the housing,
12 between the first and second webs.

1 10. A medical article sterilization device according to claim 9, further comprising a
2 pretreatment area for medical articles, the pretreatment area having a heat source to heat the
3 medical articles.

1 11. A medical article sterilization device according to claim 8, wherein the second
2 web is formed of a gas permeable material.

1 12. A medical article sterilization device according to claim 8, wherein:

2 substantially no moisture is supplied to the medical articles at the sterilization-
3 sealing station, and

4 the medical article sterilization device further comprises a pretreatment area
5 having a steam source to supply moisture to the medical articles.

1 13. A medical article sterilization device according to claim 12, wherein:
2 the sterilization-sealing station further comprises a vacuum source and a
3 controller,
4 the vacuum source evacuates the housing,
5 evacuating the housing removes moisture from the medical articles, and
6 the controller maintains the pressure in the housing so as to allow some moisture
7 to remain with the medical articles.

8 14. A medical article sterilization device according to claim 13, wherein the
9 controller maintains the pressure in the housing so as to allow the relative humidity in the
10 housing to be at least 40 % during sterilization gas exposure.

1 15. A method of sterilizing a medical article comprising:
2 preheating a medical article in a pretreatment area;
3 forming a housing in a first web;
4 loading the medical article heated in the pretreatment area into the housing
5 formed in the first web;

6 aligning a second web with the first web;
7 sterilizing the medical article located in the housing and between the first and
8 second webs;
9 after sterilizing the medical article, sealing the first web to the second web, with
10 the medical article located in the housing and between the first and second webs.

1 16. A method of sterilizing a medical article according to claim 15, further
2 comprising injecting gas into the housing, between the first and second webs, through gas
3 injection pins.

4 17. A method of sterilizing a medical article according to claim 16, wherein steam is
5 injected into the housing, between the first and second webs, through the gas injection pins.

6 18. A method of sterilizing a medical article according to claim 15, wherein steam is
7 injected into the housing, between the first and second webs.

1 19. A method of sterilizing a medical article according to claim 15, wherein:
2 sterilization and sealing are conducted at a sterilization-sealing station,
3 substantially no moisture is supplied to the medical article at the sterilization-
4 sealing station, and
5 steam is supplied to the medical article at the pretreatment area.

1 20. A method of sterilizing a medical article according to claim 19, further
2 comprising the steps of:
3 evacuating the housing at the sterilization-sealing station so as to remove
4 moisture from the medical article, and
5 maintaining the pressure in the housing so as to allow some moisture to remain
6 with the medical article.

10 21. A medical article sterilization device according to claim 20, wherein the
11 pressure in the housing is maintained so as to allow the relative humidity in the housing to be
12 at least 40 % during sterilization gas exposure.

13 22. A method of sterilizing a medical article comprising:
14 forming a housing in a first web;
15 loading a medical article into the housing formed in the first web;
16 aligning a second web with the first web;
17 injecting gas into the housing, between the first and second webs, through gas
18 injection pins;
19 sterilizing the medical article located in the housing and between the first and
20 second webs; and
21 after sterilizing the medical article, sealing the first web to the second web, with
22 the medical article located in the housing and between the first and second webs.

1 23. A method of sterilizing a medical article according to claim 22, wherein steam is
2 injected into the housing, between the first and second webs, through the gas injection pins.

1 24. A method of sterilizing a medical article according to claim 23, wherein the
2 steam is injected into housing to pressurize the housing to a pressure of 60 to 100 psia.

1 25. A method of sterilizing a medical article according to claim 24, wherein
2 the housing is evacuated before pressurizing with steam, and
3 the housing is evacuated after pressurizing with steam and then sterilizing gas is
4 supplied to the housing.

1 26. A method of sterilizing a medical article according to claim 24, wherein the
2 housing is maintained in a condition pressurized with steam for a time period of 1 to 8 minutes.

1 27. A method of sterilizing a medical article according to claim 24, wherein
2 the housing is pressurized with steam and supplied with sterilizing gas within a
3 form, fill and seal device having a sterilization-sealing station, which has an interior volume to
4 contain the housing, and
5 the housing is pressurized with steam to deliver 10 to 50 Btu of heat per cubic
6 foot of interior volume.

1 28. A method of sterilizing a medical article according to claim 22, wherein the
2 second web is formed of a gas permeable material.

1 29. A method of sterilizing a medical article according to claim 23, further
2 comprising preheating the medical article in a pretreatment area.

1 30. A method of sterilizing a medical article according to claim 22, wherein:
2 sterilization and sealing are conducted at a sterilization-sealing station,
3 substantially no moisture is supplied to the medical article at the sterilization-
4 sealing station, and
5 moisture is supplied to the medical article as steam at a pretreatment area.

1 31. A method of sterilizing a medical article according to claim 30, further
2 comprising the steps of:
3 evacuating the housing at the sterilization-sealing station so as to remove
4 moisture from the medical article, and
5 maintaining the pressure in the housing so as to allow some moisture to remain
6 with the medical article.

1 32. A medical article sterilization device according to claim 31, wherein the
2 pressure in the housing is maintained so as to allow the relative humidity in the housing to be
3 at least 40 % during sterilization gas exposure.